Summary of Safety and Effectiveness Information **Special 510(k): Device modification** **Premarket Notification, Section 510(k)**	***AEQUALIS Shoulder Fracture System*** **Tornier S.A.**

K003728

Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

DEC 2 0 2000

1) Device name

Trade name:	***AEQUALIS Shoulder Fracture System***
Common name:	Total-Shoulder System and Hemi-Shoulder System
Classification name:	Shoulder joint metal/polymer semi-constrained cemented prosthesis

2) Established name & Registration number

Name:	Tornier S.A.
Number:	9610667

3) Classification

§ 888.3660 Shoulder joint metal/polymer semi-constrained cemented prosthesis.

Device class:	Class II
Classification panel:	Orthopedic
Product code:	87 KWS

4) Device background

The present device modification submission concerns the evolution of the humeral stem, which is a part of the *AEQUALIS Shoulder Fracture System,* already legally marketed (K994392). The *AEQUALIS Shoulder Fracture* System is a typical 3-part system consisting of interchangeable humeral heads, a humeral stem and, if used as a total shoulder, a glenoid component.
The *AEQUALIS open stem for fracture* is already legally marketed for three sizes (K994392). The present *AEQUALIS stem for fracture* is the evolution of the previous one with the same indications for use already covered by the previous 510(k) clearance.
The modifications are described in part 6: Device description.

5) Equivalent / Predicate device

The determination of the substantial equivalence for this device is based on a detailed device description, performance testing and conformance with voluntary standards and the FDA Guidance: "The new 510(k) Paradigm: Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notification".

AEQUALIS Shoulder system, TORNIER SA, K952928
AEQUALIS Shoulder Fracture system, TORNIER SA, K994392
Bio-Modular, BIOMET, Inc, K872454
Total Shoulder II, ZIMMER, Inc, K790987

6) Device description

Comparison with the cleared device: Only the humeral stem of the *AEQUALIS Shoulder Fracture System* is modified. The humeral head and the glenoid component are unchanged.

The *AEQUALIS stem for fracture* is an evolution of the metaphyseal part of the previous open stem for fracture. The diaphyseal part remains unchanged with respect to the previous model of the *AEQUALIS open stem for fracture*. The modifications consist in:

1. A lateralization of the flat part of the prosthesis in order to help the anatomic reconstruction of the upper part of the humerus. The flat part is also thicker. This modification was carried out in order to increase the prosthesis mechanical resistance to break.
2. A decrease in the fin height and the remove of the two holes in the fin. These holes are no more necessary for the prehension of the prosthesis and the fixation of the prosthesis to the tuberosities. The suppression of the holes can be explained by an evolution of the reconstruction technique of tuberosities in cases of 4-part fractures of the upper humerus. Indeed, the new reconstruction technique developed by Pr. Pascal Boileau and Pr. Gilles Walch, designer-surgeons of this prosthesis, is based on suture wires getting around the prosthetic neck instead of through the holes initially designed for that purpose.
3. The surface aspect of the neck, which was initially grit-blasted, is now mirror-polished. Indeed, the suture wires getting around the prosthesis taper (see item n°2) required a smooth surface to limit the risks of breaking the sutures.

The diaphyseal part of the stem remains identical to the cleared device. The assembly of the *AEQUALIS stem for fracture* and the femoral head is not affected by this modification.
The manufacturing methods, intended use, packaging and sterilization of the subjected device are identical to the predicate device.

Overview: The usual goal of total shoulder replacement and hemi-arthroplasty of the shoulder is to restore the shoulder joint to its best working condition and to reduce or eliminate pain. The *Aequalis Shoulder Fracture System* is intended to accomplish these goals. With the *Aequalis Shoulder Fracture System*, the natural glenoid elements of the shoulder may be conserved or replaced as warranted by the state of disease or injury. Thus the *Aequalis Shoulder Fracture System* is intended for use as a total shoulder replacement system, or as a hemi-shoulder. The modular nature of the system allows for the later conversion of a primary hemi-arthrosplasty to a total shoulder replacement.

Device Description: The *Aequalis Shoulder Fracture System* is a typical 3-part system consisting of interchangeable humeral heads, a humeral stem and, if used as a total shoulder, a glenoid component.
The *Aequalis Shoulder Open stem for Fracture* is available in 3 diameters (6.5, 9 and 12), with the same length. The geometry of the metaphyseal part has been designed to allow the filling by bone graft and to improve the knitting of the bones. The goal of the metaphyseal shape is to make a "bony bridge" between the tuberosities. In order to allow extraction of the prosthesis in case of revision, two slits have been designed to break the bony bridge. Anterior-posterior fins extending from diaphyseal portion form a convex bearing area allowing adequate positioning and synthesis of the greater tuberosity. The stem is used cemented in the diaphyseal part.

The offered combinations of stem, head and glenoid sizes accommodate a wide range of anatomical variations and circumstances.

Materials: The stem is made of Titanium alloy (6Al-4V-Ti) according to ISO 5832-3. It is grit-blasted on its proximal part. The humeral head is made of Cobalt-Chromium alloy according to ISO 5832-7.

Indications: Prosthetic replacement with this device may be indicated to relieve severe pain or significant disability in degenerative, rheumatoid, or traumatic disease of the glenohumeral joint; non-union humeral head fracture; displaced 3-and 4-part proximal humeral fractures; avascular necrosis of the humeral head; or other difficult management problems where arthrodesis or resectional arthroplasty are not acceptable.

Voluntary standards: Various voluntary performance standards are used. They include Tornier S.A. Standard Operating Procedures (SOP), vendors certifications and qualification procedures, Quality system Regulations (QSR) and EN 46001 specifications and European CE marking.

Design control activities
Risk analysis method: The risk analysis is carried out during the design of a specific product, a new product or a modified product. The process of risk analysis is defined in a SOP. This is a summary of the method:
1. Identification of critical features
2. Identification of potential hazards coming from these characteristics
3. Identification of harms
4. Risk analysis: estimation of the level of the risk relating to each identified hazard.

The estimation takes into account the evaluation of the frequency and gravity degree of the harm. The combination of the two parameters gives the degree of acceptability of the risk.

The process of risk analysis uses some elements of the NF EN standard 1441.

Identification of hazards and validation activities: Based on this method, the device modification allows identifying two kinds of hazards. Comparative tests and finite element calculations allow to demonstrate that the design modification of this stem does not induce any new or higher risks compared to the previous model.

7) Applicant name & Address

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8) Company contact

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9) Submission correspondent

Mr David W. Schlerf
Buckman Company, Inc.
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10) Comparison table

Humeral stem features	Aequalis Shoulder Fracture System (Stem for fracture)	Aequalis Shoulder Fracture System (Open stem for fracture)	Aequalis Shoulder System	Bio-Modular	Total Shoulder II	SE?
Materials	TiAl6V4	Same	TiAl6V4 or CoCr	TiAl6V4	CoCr	Yes
Method of Fixation	Trunnion bearing Cemented	Same	Same	Trunnion bearing Cemented or Uncemented	Single piece Cemented or Uncemented	Yes
Indications for Use	Hemi- and Total Shoulder replacement	Same	Same	Same	Same	Yes
Standards Specifications Titanium alloy	ISO 5832-3	Same	Same	ASTM F 136	ASTM F 136	Yes
Manufacturer	TORNIER, SA	TORNIER, SA	TORNIER, SA	BIOMET, Inc	ZIMMER, Inc	-
K-number	Pending	K994392	K952928	K872454	K790987 & K802123	-

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 0 2000

Mr. David W. Schlerf
Representing Tornier S.A.
Buckman Company, Inc.
Representing Tornier
200 Gregory Lane, Suite C-100
Pleasant Hill, California 94523-3389

Re: K003728
Trade Name: Aequalis Shoulder Fracture Stem
Regulatory Class: II
Product Code: KWS and HSD
Dated: November 28, 2000
Received: December 4, 2000

Dear Mr. Schlerf:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K003728

Device name: ***AEQUALIS Shoulder Fracture System***

Indication for use:

Traumatic or pathologic conditions of the shoulder resulting in fracture of the glenohumeral joint. Including humeral head fracture and displaced 3-or 4-part proximal humeral fractures.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

NPRO for CMW

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K003728

Prescription use ✓ OR Over-The-Counter Use_____

(Per 21 CFR 801.109) (Optional format 1-2-96)